OBJECTIVES: To examine the association between continuity of care and risk of potentially inappropriate concomitant medication (PICM) in continuous non-steroidal anti-inflammatory drug (NSAID) users. **METHODS:** Longitudinal Health Insurance Database 2005 (LHID2005) which contains one million of randomly sampled beneficiaries from National Health Insurance (NHI) in Taiwan was used to identify continuous NSAID users who were prescribed with NSAID more than 30 days in 2005. NSAID's PICM was defined as if there are significant drug-drug interactions (DDI) event based on Drug Interaction Facts. Continuity of care (COC) index was used to measure the degree of continuous care for these NSAID users. Multiple logistic regression analysis was then applied to estimate the association between continuity of care and PICM. **RESULTS:** There were 52,010(5.2% of LHID2005) beneficiaries using NSAID more than 30 days in 2005, and 20.2% of continuous NSAID users had PICM. Of which, Beta blocking agents was the most frequently prescribed and accounted for 8.79% of total PICM. Compared with lower level of COC, the odds ratios of PICM were 0.89(95% confidence interval 0.84-0.94) and 0.76(95% confidence interval 0.71-0.80) respectively for medium and high levels of continuity of care when personal, physician and institutional characteristics were controlled in logistic regression. **CONCLUSIONS:** PICM was common for continuous NSAID users in Taiwan, especially in those who had lower level of COC. While the consequence of PICM has to be investigated further, health policy directed to improvethe continuity of caremay reduce the risk of drug interactions in NSAID users.

PSY65

REAL WORLD TREATMENT PATTERNS IN CHRONIC LYMPHOCYTIC LEUKEMIA PATIENTS IN THE UNITED STATES - RITUXIMAB, THE MOST COMMONLY USED AGENT

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OBJECTIVES: CLL is an indolent incurable lymphoma with a widely variable disease course. Its treatment is therefore quite heterogeneous. The goal of this project was to evaluate the real-world use of individual agents or combination regimens across all lines of therapy in CLL during the years 2010-2013 in order to understand the current treatment paradigm of CLL. **METHODS:** Treatment records for 110,000 cancer patients and over 6.7 million drug administrations were evaluated between August 2010 and July 2013 at US cancer care facilities participating in a nationwide, commercially available chemotherapy order entry system called IntelliDose®. IntelliDose® captures patient demographics, stage, and details of chemotherapy treatment. The composition of the 820 oncologists who use IntelliDose® is much like the overall population of oncologists in the US, including 54% in private practice and 41% community hematologist/oncologists. The CLL patients sampled by IntelliDose® were projected to a national level for the interpretation of the results. **RESULTS:** The average monthly number of CLL patients undergoing any line of treatment was 7,736 (SD= 565). Of the 3,380 patients receiving first line therapy, the majority of patients (n=810; 24%) were receiving Bendamustine-Rituximab (BR), followed by Fludarabine-Cyclophosphamide -Rituximab (FCR) (n=716; 21%).For relapsed CLL, BR was also the most common regimen (18-33% of monthly use), followed by R monotherapy (7- 16% of monthly use). Across all lines of therapy, BR is the most common regimen used (14-32% monthly use) followed by R alone as the second most common regimen (18-25% of monthly use). **CONCLUSIONS:** Rituximab is the most frequently used agent either as a single agent or in combination, in all lines of CLL treatment in the US. Single agent Rituximab is commonly used in CLL therapy in 2nd line and above, despite low reported response rates in the literature.

PSY66

EIGHT YEARS EXPERIENCE WITH AVAILABILITY AND UPTAKE OF ORPHAN DRUGS WITH OR WITHOUT PRIOR EU ORPHAN DESIGNATION IN SLOVAKIA

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OBJECTIVES: There are currently 68 orphan drugs with European marketing authorization with orphan designation and 75 orphan drugs without prior orphan designation in EU. Current Health technology appraisal recommendations in Slovak Republic do not include any specific guidelines for reimbursement of orphan drugs (OD). Orphan drug reimbursement decisions are made on case-to-case basis and no clear rules are currently present. We evaluated market uptake of selected 90 orphan drugs and compared it to total market evolution from 2005 to 2012. **METHODS:** Our analysis include volume and sales evolution of 90 orphan drugs in Slovak Republic from 2005 to 2012 using Health database and publicly available data. **RESULTS:** Results show that cumulative 8-years expenditure for selected list of ODs is over 1,1 billion EUR. The peak sale was reached in 2012 and that sale accounted for 18,6% from total pharmaceutical spending in 2012. The highest sales growth was in 2006 with 33,4% compared to previous year. Until 2009, we have seen strong double-digit growth following by still high single digit growth in 2010 (6,1%) and 2012 (7,6%). Total expenditure represented 10,7%, 12,4%, 12,8%, 13,5%, 14,7%, 15,2%, 16,5% and 18,6% of total medicine expenditure from 2005 to 2012 in SK, respectively. The highest expenditure burden lies on one ATC category: L- antineoplastic and immunomodulating agents with 57% share. **CONCLUSIONS:** The uptake of orphan drugs is according to EU standards very high, but it must be noted that many ODs are locally off-patent and generics expand the market. Secondly, we included into our selection ODs with and without prior orphan designation. Nevertheless, it is important to make more detailed analysis and advocate for prudent reimbursement rules for orphan drugs, mainly from local HTA perspective.

PSY67

JUDICIARY BRANCH IN BRAZILAN ANALYSIS OF JUDICIAL DECISIONS INVOLVING ETANERCEPT, INFLIXIMAB AND ADALIMUMAB

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BACKGROUND:: Worldwide the judiciary branch has been an active player in public health policies, especially regarding drugs. In Brazil, this is a huge concern. This abstract presents an evaluation of the judicial response to cases regarding three biological drugs: etanercept (enbrel), infliximab (remicade) and adalimumab (humira), all TNF inhibitor agents for the treatment of patients with autoimmune diseases. **OBJECTIVES:** To identify the prevalence of scientifically grounded judicial decisions and the knowledge of Brazilian judges regarding clinical protocols, evidence-based medicine and health technology assessment. **METHODS:** Electronic databases of the Supreme Court (STF), the Superior Court of Justice (STJ) and all Federal Regional Courts (TRFs) were searched using the keywords "etanercept" (enbrel), "infliximab" (remicade) and "adalimumab" (humira). **RESULTS:** 102 judicial decisions were found: 6 collegial judgments (6%) and 96 monocratic decisions (94%). Of these, 29 were excluded due to procedural reasons (28%) and 73 met the eligibility criteria (72%). Of those 73, 69 decisions (95%) determined that government have to supply the medications. Only 2 decisions (2.5%) considered it improper to supply the drug due to a lack of evidence regarding its effectiveness. Additionally, 2 decisions (2.5%) determined the need for forensic expertise. Out of the 73 decisions examined, 65 did not rely on scientific evidence. Another 2 referred to evidence-based medicine, without, however, taking it as a plea for the decision-making process. Only 2 decisions considered evidence as a basis for decision-making. On the other hand, just 4 decisions referred to expert medical opinions. **CONCLUSIONS:** The judiciary branch does not rely on scientific evidence or health technology assessment as a tool to the decision-making process. In order to preserve the right to health and the public health system´s sustainability, it is necessary to employ medical evidence methods in judicial decisions.

PSY68

CHANGES AND VARIATION IN CONDITIONS FOR NEWBORN SCREENINGSTATE-SPECIFIC CONDITIONS SCREENED VERSUS ACMG RECOMMENDATIONS CONTRASTED WITH EUROPE

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OBJECTIVES: The American College of Medical Genetics (ACMG) recommended expanding and standardizing the group of rare conditions in US newborn screening (NBS) in 2006. This research examines the correspondence between ACMG recommendations and state implementation and contrasts this with Europe. **METHODS:** We collected historical data on conditions screened in state programs. We defined conditions as Recommended (R list) based on whether a condition was in ACMG's Core of 29 conditions plus 25 secondary conditions groupings. We then assessed each state's (plus D.C.) correspondence with ACMG recommendations. We also collected data from Europe. **RESULTS:** The mathematical union of all conditions screened in the 51 US geographies is 74. In 2005, prior to the expansion, geographies varied in NBS screening from a low of 4 conditions to a high of 46 (mean= 24). This represented a significant increase over that from 10 years earlier (mean=5; range= 0-8). Currently, the mean number of conditions screened is 48 (range 31-64). Twenty geographies screen for at least 50 of the 54 ACMG recommendations. Only 3 geographies screen for the complete R list; these 3 and 22 others screen for additional conditions not on the R list. All US geographies screen for more than 20 conditions. In contrast, recent European data indicate a range from 1 to 29 conditions among 37 geographies reporting data (mean= 8), with only 6 geographies reporting 20 or more. **CONCLUSIONS:** The expansion of NBS in the US has been a success in terms of correspondence with ACMG recommendations with 20 of the 51 US geographies adhering to at least 50 of the original 54 ACMG recommendations. The contrast with European geographies raises questions about the expansion. Whether it is a positive development depends on its costs and health implications.

PSY69

CONSEQUENCES OF PATIENT ACCESS RESTRICTIONS TO BRANDED OXYCODONE HYDROCHLORIDE CONTROLLED-RELEASE ON HEALTH CARE UTILIZATION AND COSTSA CASE-CONTROL STUDY OF UNITED STATES HEALTH PLANS

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OBJECTIVES: This study evaluated the impact of increasing patient access restrictions to branded oxycodone hydrochloride controlled-release tablets (OXY) on physician office visits, pharmacy utilization and costs. **METHODS:** This retrospective case-control study of IMS's medical/pharmacy claims and Formulary Focus database analyzed adult patients with ≥1 extended-release and long-acting opioid Rx claim indexed between 1/1/2009 and 12/31/2011. Patients with ≥6 month's observation in pre-restriction or post-restriction periods were analyzed. Cases included patients in commercial or Medicare plans imposing access restrictions (tier change [TC] or prior-authorization [PA]), thus forming four groups: commercial PA (Com-PA), commercial TC (Com-TC), Medicare PA (MC-PA) and Medicare TC (MC-TC). Controls were selected from plans without access restrictions and were matched based on demographics, clinical characteristics, payer type and index quarter. Pharmacy and office visit utilization and costs were measured for 6 months following each patient's index date, comparing the pre- to post-restriction period within each study group. Bootstrapping t-test and generalized linear models were utilized to test the differences in resource utilization and costs. **RESULTS:** The study groups were approximately 55 years old and 60% female. A significant increase in 6-month office visits was observed from the pre to the post-restriction period in plans imposing access restrictions: COM-PA (2.13, p<0.001), COM-TC (1.29, p=0.017), MC-PA (0.81, p=0.021), MC-TC (1.00, p<0.001). Total (medical+pharmacy) mean pre to post-restriction cost increases of $1,019 (p<0.001), $433 (p=0.076), $684 (p<0.001) and $348 (p<0.001) were also observed in the access restricted groups, respectively. No significant change in office visits or costs were observed in the COM-TC, MC-PA or MC-TC control groups, however, an increase was observed in the control group matched to the COM-PA group for office visits (2.01, p=0.001) and total costs ($969, p<0.001). **CONCLUSIONS:**